

Japan approves Avastin for brain cancer treatment

18 June 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Roche announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Avastin (bevacizumab) for the treatment of malignant glioma, including newly diagnosed glioblastoma (GBM) in combination with radiotherapy and temozolomide chemotherapy, and as monotherapy for treatment of recurrent GBM and certain other types of high grade glioma following prior therapy.

Current treatment options for malignant glioma are limited, and Avastin represents the first new medicine approved worldwide for newly diagnosed glioblastoma, the most common and aggressive form of primary brain cancer, in the last eight years. "This approval of Avastin is important news for people in Japan who have been diagnosed with glioma and glioblastoma because aggressive brain cancer can significantly reduce a person's quality of life and the ability to perform everyday activities," said Mr Hal Barron, Roche's Chief Medical Officer and head of Global Product Development. "People with newly diagnosed glioblastoma who received Avastin plus radiotherapy and temozolomide chemotherapy in the pivotal study experienced a significantly longer period of time without their cancer worsening."

The approval was based on data from three clinical studies in GBM: the phase II BRAIN study; Japanese phase II study (JO22506); the pivotal phase III AVAglio study, which demonstrated that when Avastin was added to standard treatment, patients lived significantly longer without their disease getting worse. Final results from the AVAglio study in newly diagnosed GBM patients were recently presented at the 49th annual meeting of the American Society of Clinical Oncology in Chicago.

Applications for first-line treatment have been filed with the health authorities in the EU and Switzerland. Avastin is marketed in Japan by Chugai Pharmaceutical, a member of the Roche Group. Avastin for malignant glioma was designated as an orphan drug in Japan in May 2013, as the estimated number of newly diagnosed malignant glioma and GBM patients per year is about 1,700.